

November 1, 2018

SENT VIA EMAIL

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: CMS-1694-P Fiscal Year 2020 Inpatient Prospective Payment Systems for Acute Care Hospitals – Coding and MS-DRG Classification for Extracorporeal Membrane Oxygenation (ECMO)

Dear Administrator Verma,

The undersigned specialty societies are writing to request that all Extracorporeal Membrane Oxygenation (ECMO) codes be reassigned back to Pre-Major Diagnostic Category (Pre-MDC) Medicare Severity Diagnosis Related Group (MS-DRG) 003 for FY 2020 and that the Centers for Medicare and Medicaid Services (CMS) take steps to mitigate the negative impact of these changes in 2019. We have significant concerns with the process, the lack of transparency, and the lack of opportunity to provide public comment on the MS-DRG assignment for services related to ECMO for FY-2019.

Below, we provide evidence demonstrating that all ECMO patients are critically ill and that the cost and complexity of care provided to these critically ill patients is unrelated to the method of cannulation (central, peripheral open cutdown, peripheral percutaneous). Patients on ECMO are on life support analogous to cardiopulmonary bypass. Patients who are eligible for ECMO have a high likelihood of death without treatment. The ECMO MS-DRG reassignment for FY 2019 that went into effect on October 1, 2018 will negatively impact patient access to care by affecting a large number of providers and institutions. The ECMO MS-DRG reassignment was made without appropriate notice or comment and it will force many hospitals to discontinue their ECMO programs and cost the lives of adult and pediatric patients who might otherwise have been saved by this technology.

The undersigned specialty societies have major concerns with CMS's process in implementing this change. First, the modification in the ECMO International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) codes involved switching from a single code (5A15223) to three separate PCS codes differentiated by the mode of vascular cannulation (central or peripheral) and the indication (cardiac or respiratory support). The result is that MS-DRG assignment for ECMO support is now predicated upon those codes, resulting in differential reimbursement based on the cannulation approach. Unfortunately, this was done without any objective information suggesting different levels of costs or resource expenditure for these different scenarios. Secondly, the new peripheral cannulation ICD-10 PCS codes accepted by both the ICD-10 Coordination and Maintenance Committee and CMS fail to create ICD-10 PCS codes differentiating peripheral open cutdown and percutaneous methods. The lack of peripheral open cutdown ICD-10 PCS ECMO cannulation codes is a major deficiency.

With this in mind, we request that CMS do the following:

1. Meet with the medical specialty societies listed below to find a way to mitigate the inappropriate negative financial impact of these changes for FY 2019 in order to prevent closure of ECMO programs and other unintended consequences including denying patients access to a lifesaving procedure.
2. Reassign all ECMO ICD-10 PCS codes (5A1522F, 5A1522G and 5A1522H), regardless of the cannulation method, to Pre-MDC MS-DRG 003 for FY 2020.

General Comments

- 1. Meet with the medical specialty societies listed below to find a way to mitigate the inappropriate negative financial impact of these changes for FY 2019 in order to prevent closure of ECMO programs and other unintended consequences including denying patients access to a lifesaving procedure.***

The changes made by CMS were implemented outside of the regular proposed rulemaking process and we have little recourse in asking CMS to address these problems in the short term. We request a face-to-face meeting with the appropriate staff at CMS to discuss possible solutions to mitigate the inevitable elimination of ECMO services due to program-ending reimbursement reductions that this new policy will create.

- 2. Reassign all ECMO ICD-10 PCS codes (5A1522F, 5A1522G and 5A1522H), regardless of the cannulation method, to Pre-MDC MS-DRG 003 for FY 2020.***

We plan to ask the ICD-10 Coordination and Maintenance Committee at its March 2019 meeting to rectify the deficiencies in the ECMO ICD-10 PCS codes. However, regardless of any changes to the ICD-10 PCS codes for FY 2020, the undersigned specialties still request that all ECMO continue to be assigned to Pre-MDC MS-DRG 003 until additional data on central, peripheral open cutdown and peripheral percutaneous ECMO cannulation approaches are available and any proposed revisions to MS-DRG assignment can be more appropriately addressed through the rulemaking process.

ECMO Overview

Peripheral ECMO involves insertion of cannulae via the femoral, cervical, or axillary vessels either percutaneously or by means of open surgical cutdown. The new ECMO procedure codes fail to recognize that there are two peripheral approaches, with the open cutdown always being surgical. Patient specific anatomic considerations concerning the peripheral vessels, *and not surgeon preference*, determine whether the peripheral access is accomplished percutaneously or by open cutdown. Peripheral ECMO via open cutdown cannulation is most commonly done in the operating room. Establishment of percutaneous peripheral ECMO can be done in the operating room, the cardiac catheterization lab or in the intensive care unit (ICU). Regardless of where the percutaneous ECMO cannulation procedure is performed, the situation is typically emergent, and often involves a patient so hemodynamically unstable that transfer to an operating room is unsafe. The notion that percutaneous cannulation for ECMO is associated with less sick patients is fallacious and, in fact, may frequently be a marker for quite the opposite, i.e. patients with the highest acuity receiving an emergent procedure bedside.

As with central ECMO patients, the peripheral ECMO patient is supported in the ICU and maintained on ECMO for days to weeks until organ recovery, transition to longstanding organ replacement, or death. With both central and peripheral modes of cannulation, patients are extremely ill, require substantial multidisciplinary resources, and typically experience prolonged hospital lengths of stay. For both central and peripheral open cutdown ECMO, removal of the cannulas occurs in the operating room with direct exposure and visualization to repair the blood vessels. Because of the large cannula size, removal of peripheral percutaneous cannulas usually involves surgically exposing and repairing the vessels in the operating room.

Timeline of Changes to ECMO ICD-10 PCS Codes

The process used for MS-DRG assignment of three new ICD-10 PCS codes for FY 2019 fell outside of the normal CMS process and did not provide any opportunity for public comment. In the FY 2019 Inpatient Prospective Payment System (IPPS) proposed rule, CMS noted that it had received a request to review claims data for procedures involving ECMO in combination with insertion of a percutaneous short-term external heart assist device for appropriate MS-DRG assignment. Without supporting data, the requestor stated that ECMO procedures performed via percutaneous cannulation are less invasive and less expensive than traditional methods of ECMO and are performed on patients who are less ill. The requester suggested that cases reporting a procedure code for ECMO in combination with the insertion of a percutaneous short-term external heart assist device could be reassigned from Pre-MDC MS-DRG 003 (*ECMO or Tracheostomy with Mechanical Ventilation >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedure*) to MS-DRG 215 (*Other Heart Assist System Implant*). CMS reviewed Pre-MDC MS-DRG 003 cases in the September 2017 update of the FY 2017 MedPAR file for those reporting ECMO with and without the insertion of a percutaneous short-term external heart assist device and cases in MS-DRG 215 for procedure codes 02HA3RZ (*Insertion of short-term external heart assist system into heart, percutaneous approach*) and 02HA4RZ (*Insertion of short-term external heart assist system into heart, percutaneous endoscopic approach*). While the average length of stay and average costs for cases where procedure code 5A15223 (*Extracorporeal membrane oxygenation, continuous*) was reported with procedure code 02HA3RZ or procedure code 02HA4RZ in Pre-MDC MS-DRG 003 is lower than the average length of stay and average costs for cases where procedure code 5A15223 was reported alone, CMS was unable to determine from the data if those ECMO procedures were performed percutaneously in the absence of a unique code. The requester also noted that ICD-10-PCS, did not have a specific procedure code to identify percutaneous ECMO and hospitals were only able to report ICD-10-PCS procedure code 5A15223, which was assigned to Pre-MDC MS-DRG 003 which may inappropriately result in a higher payment. The commenter indicated that a request to create new ICD-10-PCS procedure codes specifically for percutaneous ECMO would be submitted.

In the IPPS for FY 2019 proposed rule, CMS proposed to keep ECMO cases as assigned in the current MS-DRG because the CMS clinical advisors indicated that, until there is a way to specifically identify percutaneous ECMO in claims data, it would not be clear what proposal to make. Based on the FY 2019 IPPS proposed action, many organizations determined that it was unnecessary to submit public comment on this specific issue, but would monitor CMS actions in future rule-making.

New ECMO codes were submitted for consideration at the March 2018 ICD-10 Coordination and Maintenance Committee meeting resulting in the deletion of the existing ECMO ICD-10-PCS code and the addition of three new ECMO ICD-10-PCS codes, one for central ECMO and two codes for peripheral

ECMO (VA and VV). A major deficiency in the proposed peripheral ECMO cannulation codes was the absence of ICD-10 PCS codes for peripheral vessel open cutdown, which, like central cannulation, is almost always an OR procedure. The one central and two peripheral percutaneous codes, without a peripheral open cutdown PCS code, were approved for implementation on Oct. 1, 2018.

Because the ICD-10-PCS codes were not finalized at the time of the FY 2019 IPPS proposed rule but were approved for implementation on Oct. 1, 2018, CMS used their annual process of assigning new procedure codes to major diagnostic categories (MDCs) and MS-DRGs after the public comment period for FY 2019 IPPS had passed. Because the procedure codes were not yet approved, there were no proposed MDC, MS-DRG, or O.R (surgical) and non-O.R. (medical) designations for these new procedure codes included for comment in the FY 2019 IPPS proposed rule. In determining MS-DRG assignments for the three new ECMO ICD-10-PCS codes, the CMS clinical advisors concluded that central ECMO is extremely invasive and carries significant risks for complications. Although percutaneous (peripheral) ECMO also carries risks, CMS concluded that those risks differ from those of central ECMO because the procedure can be performed in the ICU or at the bedside. As a result, CMS designated the new central ECMO PCS code (5A1522F) as a surgical procedure and assigned it to Pre-MDC MS-DRG 003. The new peripheral ECMO PCS codes (5A1522G and 5A1522H) were designated as medical procedures and assigned to MS-DRGs 207, 291, 296 and 870. Because the only avenue for comment readily available to the public on ECMO and DRG assignment was in the FY 2019 IPPS proposed rule, where CMS stated its intent to keep ECMO cases in the current MS-DRG assignment, the timing of the creation and approval for the new ECMO ICD-10-PCS codes for implementation on Oct. 1, 2018 made it impossible for the public to comment on the ECMO MS-DRG changes by CMS in the FY 2019 IPPS final rule and did not follow CMS process.

The newly created ICD-10 PCS codes are inadequate to capture all the ways ECMO can be provided. ECMO is an advanced life support technique used in critically ill patients. While on ECMO, a patient's blood is continuously circulated from the body through the ECMO machine where it is oxygenated and then returned back into the patient, thus temporarily replacing their heart and/or lung function. ECMO is a modification of the cardiopulmonary bypass system used for open heart surgery and is used to support patients who are at imminent risk of death from severe heart, lung or heart-lung failure. ECMO is typically applied for days or weeks, until the damaged heart or lungs recover or to allow the patient to be transitioned to longstanding organ replacement such as heart transplant or implantable ventricular assist devices (VAD). Treatment with ECMO is very complex and requires sophisticated institutional infrastructure and experienced multidisciplinary care teams to manage the patient and the ECMO circuit. Initiation of ECMO requires vascular access, which can be accomplished via insertion of cannulae directly in the cardiac chambers or great vessels (central access), or by insertion of cannulae into the femoral, cervical, or axillary vessels (peripheral access). There are specific CPT codes (33952-33956) that represent the physician work for the procedures associated with these different methods of cannulation (central, peripheral open cutdown, and peripheral percutaneous).

The changes in the MS-DRG assignments for the ICD-10 PCS codes were based, in part, on CMS clinical advisors' assertion that ECMO via central access requires a new thoracotomy or sternotomy in the operating room and is "extremely invasive and carries significant risks for complications," making central ECMO initiation more resource intensive because of the complex surgery required. However, although, central ECMO patients are critically ill, central ECMO is most commonly used when the heart has not recovered enough near the end of a cardiac surgical operation and the patient cannot come off

cardiopulmonary bypass. Central ECMO, its cannula placement, and its initiation most commonly occurs in patients who are already in the operating room and their chest is already open. The cardiopulmonary bypass circuit is removed and replaced with an ECMO circuit. After the ECMO circuit is attached and ECMO initiated, it is maintained for days to weeks with the patient in the ICU. Patients who can be successfully weaned from ECMO support typically remain hospitalized for additional weeks during the resolution of their critical illness. The clinical advisors' assertion that, because the peripheral ECMO procedures were done in the catheterization laboratory, ICU or at bedside the risk is different, is incorrect. Although the cannulation method is different, all other risks for the patients are similar.

Data Available in Evaluating Central versus Peripheral ECMO

Founded in 1989, The Extracorporeal Life Support Organization (ELSO) is an international non-profit consortium of health care institutions who are dedicated to the development and evaluation of novel therapies for support of failing organ systems including over 500 ECMO centers. ELSO maintains a registry of patients treated in over 500 ECMO centers internationally (now greater than 100,000 cases including infants, children, and adults). The ELSO Registry (the Registry) is considered the gold standard for outcomes in patients supported on ECMO.

The Registry contains data regarding characteristics of patients placed on ECMO, the techniques utilized, resource utilization, and outcomes. These data include the methods of vascular access and the primary indication for ECMO (cardiac or respiratory). There are approximately 3,000 United States adult ECMO cases entered into the Registry each year. Table 1 demonstrates ELSO Registry data from January 2013-July 2018 for adult patients in the U.S. Even with ECMO initiation in patients felt to be at imminent risk of death, ECMO used for support of the patient's heart has a survival rate of approximately 40% and when used for respiratory support, the survival rate is approximately 60%. While longitudinal survival is not provided in the ELSO registry, multiple expert single center reports have demonstrated excellent long-term survival in those patients successfully discharged.

Data from the Registry indicates that Peripheral cannulation was used for 96% of pulmonary patients and 77% of cardiac patients. Until the recent MS-DRG change, all of these patients were assigned to Pre-MDC MS-DRG 003. The time on ECMO and length of stay was similar for peripheral or central access. For patients placed on ECMO for cardiac support, there is no evidence from the Registry data that peripherally cannulated (open or percutaneous) patients are less ill. In particular, the average length of hospital stay for both centrally and peripherally cannulated patients is very long and there is no difference in survival rates. Duration of ECMO support is also similar for central and peripherally cannulated patients, further demonstrating that the patient populations are similar. Table 2 shows the CMS relevant MS-DRG assignments related to ECMO and the CMS lengths of stay. Note the markedly higher hospital lengths of stay for all categories of Registry patients (Table 1) compared with CMS' length of stay (Table 2). Without doubt, MS-DRG assignment based upon ICD-10 PCS codes related to the vascular cannulation approach does not accurately reflect the institutional requirements for maintaining a safe ECMO program.

The Registry demonstrates that patients cannulated peripherally are not less ill than those cannulated centrally and that the resources required to manage them are no less intense. Additional Registry data provided in Appendix A shows similarity in acuity of illness prior to ECMO initiation, including lactate levels, the use of vasoactive medications, and the requirement for cardiopulmonary resuscitation. It is

this high acuity of illness and complexity of ECMO support that drives costs of care, not the method of vascular cannulation.

Table 1

ELSO Registry Data from Jan 2013 - July 2018 for ECMO in Adults in the U.S.					
	# CASES	% CASES	ECMO DAYS	Hosp Length of Stay	OUTCOME (% Survived)
Respiratory Support	6788	40% overall			60
Peripheral	6490	96%	11.8	47	61
Central	298	4%	13.4	53	45
Cardiac Support	10,033	60% overall			35
Peripheral	7723	77%	5.3	31	39
Central	2310	23%	6	69	33
Total Adult ECMO cases	16,821	100	8 days avg	70 days avg	50

Table 2

Medicare MS-DRGs, relative weighting factors, and geometric and arithmetic mean length of stay for ECMO (Table 5 - FY 2019 Final)						
MS-DRG	MDC	TYPE	MS-DRG Title	Weights	Geometric mean LOS	Arithmetic mean LOS
003	PRE	SURG	ECMO OR TRACH W MV >96 HRS OR PDX EXC FACE, MOUTH & NECK W MAJ O.R.	18.2974	23.4	30.1
207	PRE	SURG	ECMO OR TRACH W MV >96 HRS OR PDX EXC FACE, MOUTH & NECK W MAJ O.R.	5.5965	12.0	13.9
291	05	MED	HEART FAILURE & SHOCK W MCC OR PERIPHERAL EXTRACORPOREAL MEMBRANE OXYGENATION (ECMO)	1.3454	4.1	5.2
296	05	MED	CARDIAC ARREST, UNEXPLAINED W MCC OR PERIPHERAL EXTRACORPOREAL MEMBRANE OXYGENATION (ECMO)	1.5355	2.0	3.2
870	18	MED	SEPTICEMIA OR SEVERE SEPSIS W MV >96 HOURS OR PERIPHERAL EXTRACORPOREAL MEMBRANE OXYGENATION (ECMO)	6.2953	12.4	14.4
Additional DRG Discussed for ECMO in FY2019 IPPS Proposed Rule						
215	05	SURG	OTHER HEART ASSIST SYSTEM IMPLANT	12.8861	5.2	8.7

Hospital Costs

Costs associated with ECMO are totally unrelated to the method of vascular cannulation. They can result from the medical complexity of patients on ECMO, the extensive involvement of a multidisciplinary team to provide care, the sophistication and cost of the ECMO device, as well as prolonged ICU management, and subsequent hospital care. The institutional resources required to care for ECMO patients is less related to the mode of cannulation and more related to infrastructure requirements, acuity of patient illness, and resulting prolonged hospitalization. Financial data from Mayo Clinic, University of Michigan, University of Rochester, Florida Hospital, Washington University and Vanderbilt demonstrate that hospital charges are substantial for the care of adult ECMO patients irrespective of whether the patient is centrally or peripherally cannulated. For patients cannulated centrally, total hospital charges per patient were \$834,704 (+/- \$382,901) as compared to patients cannulated peripherally with total hospital charges per patient of \$737,025 (+/- \$370,837).

We therefore recommend that all patients placed on ECMO, regardless of the method of vascular cannulation, be reassigned back to Pre-MDC MS-DRG 003 to reflect the actual length of stay and cost of care demonstrated in the data provided.

Summary

MS-DRG assignment of ECMO patients based upon the method of vascular cannulation as CMS has done in the FY 2019 IPPS will have a substantial negative financial impact on medical centers providing these services. We have been told many ECMO centers will be unable to absorb the negative financial impact, resulting in closure of their programs, and reduced availability of timely ECMO initiation for critically ill patients. Additionally, these negative impacts may shift responsibility of managing these patients to larger ECMO programs in tertiary care centers, further increasing their financial burden. The likely closure of ECMO programs because of CMS's actions will result in an increasing number of adults and children dying who would otherwise benefit from this life-saving care.

The undersigned specialty societies appreciate the opportunity to provide comment on ECMO, an important lifesaving intervention. Again, we recommend that CMS take the following actions:

- 1. Meet with the medical specialty societies listed below to find a way to mitigate the negative financial impact of these changes for FY 2019 in order to prevent closure of ECMO programs and other unintended consequences including denying patients access to a lifesaving procedure.**
- 2. Reassign all ECMO ICD-10 PCS codes (5A1522F, 5A1522G and 5A1522H), regardless of the cannulation method, to Pre-MDC MS-DRG 003 for FY 2020.**

November 1, 2018
Administrator Verma
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Thank you for the opportunity to provide feedback on this important topic. Please contact Courtney Yohe, Director of Government Relations at cyohe@sts.org or 202-787-1230 should you need additional information or clarification.

Sincerely,

American Academy of Pediatrics
American Association for Thoracic Surgery
American College of Cardiology
American College of Chest Physicians
American Society of ExtraCorporeal Technology Board of Directors
American Society of ExtraCorporeal Technology Mechanical Circulatory Support Committee
American Thoracic Society
Extracorporeal Life Support Organization
Heart Failure Society of America
Society for Cardiovascular Angiography and Interventions
Society of Cardiovascular Anesthesiologists
Society of Critical Care Medicine
The American Academy of Cardiovascular Perfusion
The American Society of Anesthesiologists
The Society of Critical Care Anesthesiologists
The Society of Thoracic Surgeons

Appendix A

Severity of Illness in Adult ECMO World-Wide Data 2013 – 2017
(Approximately 80% are U.S. Patients)

	Cardiac or VA ECMO After Cardiac Arrest		Respiratory	
	peripheral	central	peripheral	central
Age, in years, Number of cases	56.8 [45.1-65.5]	58.45 [46.4-67.6]	48 [34.3-59.2]	53.8 [37.1-62.6]
Lactate	7.1 [3.4-12]	6.6 [3.1-11.3]	2.3 [1.3-4.9]	3.1 [1.6-9] (42)
pH	7.25 [7.11-7.36]	7.28 [7.18-7.36]	7.23 [7.13-7.33]	7.27 [7.16-7.36]
Venous Saturation	58 [45 -61]	58 [46-70]	67 [55-78]	61.5 [52.5-75]
Systolic Blood Pressure	80 [65-98]	79 [61-95]	101 [86-121]	86 [72-104]
Diastolic Blood Pressure	50 [40-61]	48 [37-60]	56 [48-67]	55 [44.5-64]
Mean Blood Pressure	60 [48-71]	58 [47-70]	70 [60-81]	65 [55-75]
Systolic Pulmonary Pressure	40 [32-51]	36 [28-47]	45 [35-57]	40 [30-53]
Pulmonary Capillary Wedge Pressure	23 [18-30]	22 [16-28]	16 [11-24]	16 [11-33]
Intubation to ECMO Hours	6 [1-20]	10 [5-23]	35 [9-112]	26 [7-139]
Hours ECMO	96.5 [44-174]	110 [53-190]	189 [95-354]	128 [53-312]
Admit to Discharge (days)	24 [13-42]	30 [17-51]	27 [15-46]	43 [27-70]
Pre-ECLS Arrest	48.3	29.0	8.6	9.7
Dobutamine	17.3	14.5	4.6	7.0
Dopamine	18.5	13.6	4.2	9.9
Norepinephrine	49.1	48.2	55.9	45.0
Epinephrine	58.3	55.4	20.3	46.3
Phenylephrine	0.5	0.3	0.1	0.4
Vasopressin	1.3	0.4	4.6	7.0
Milrinone	14.7	25.5	4.3	20.2
Vasoactive	58.0	67.2	48.0	60.7
Neuromuscular Blockers	36.8	23.2	45.3	28.1
Bicarbonate Infusion	20.2	16.7	10.0	14.5
Inhaled Nitric Oxide	6.5	12.3	16.0	23.1
Died	59.5	64.5	39.4	55.0